K082855

510(k) summary

MENICON PROGENT PROTEIN REMOVER FOR RIGID GAS PERMEABLE CONTACT LENSES

December 2009

1. Applicant Information

MAR - 9 2010

Menicon Co., Ltd.
21-19, Aoi 3-chome,
Naka-ku, Nagoya, Aichi 460-0006
JAPAN
Contact Person: Takahiro Ochi
Telephone No.: +81-52-937-5021
Fax No.: +81-52-935-1121
E-mail: t-ochi@menicon-net.co.jp

2. Device Information

Classification name: Rigid gas permeable contact lens care products
Device classification: Class II
Regulation number: 21 CFR 886.5918
Product code: MRC
Proprietary name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

3. Predicate Devices

Menicon claims substantial equivalence to Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses previously cleared under K002140.

Substantial equivalence is also claimed to the Boston® Cleaner cleared under P820069. The Boston Cleaner product is an RGP lens cleaner which is a potential irritant if placed directly into the eye, but sold over-the-counter to patients for in-home use.

4. Description of device

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses is the mixture of two sterile solutions, Progent A (sodium hypochlorite, sodium carbonate, sodium hydroxide, purified water) and Progent B (potassium bromide, sodium carbonate, purified water). Progent A and B are mixed in a Menicon SP Vial. Allow lenses to soak in the Progent solution mixture for 30 minute. Soaking for longer than 30 minutes is not recommended. Progent Rinsing Solution (sterile purified water) is

provided for rinsing the lenses and SP vial. The Progent treatment is recommended every two weeks. The frequency may vary according to the condition of your lens. Follow your eye care professional's directions (to a maximum of every 5 days.

5. Indications for use

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans and removes protein deposits from fluorosilicone acrylate RGP contact lenses.

6. Substantial equivalence

The claim of substantial equivalence to the previously cleared Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses is based on the fact that the product is the same formulation. Only the indications and directions for use have been modified. The indications have been modified to remove disinfection and the restriction for professional in-office use only. The directions for use have been modified to enhance the safety for use by patients.

The applicant performed toxicological testing and clinical testing of the instructions for use to support the claim of substantial equivalence.

The additional claim of substantial equivalence to the Boston® Cleaner is based on the indications for use as an RGP lens cleaning product which is a potential irritant if placed directly into the eye, but is sold directly to patients for in-home use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Foresight Regulatory Strategies, Inc.
c/o Beverly D. Venuti, Ph.D., R.A.C.
Staff Consultant
187 Ballardvale Street
Suite 180
Wilmington, MA 01887-4461

MAR - 9 2010

Re: K082855
Trade/Device Name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC
Dated: February 26, 2010
Received: March 1, 2010

Dear Dr. Venuti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082855

Device Name: Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses

Indications for Use:

Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses, when used as directed, cleans and removes protein deposits from fluorosilicone acrylate rigid gas permeable contact lenses.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ming-Chuen Shih

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K082855